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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,246	04/24/2000	Gregory D. Jay	21486-026 CIP	7464
30623	7590	11/03/2004	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			MITRA, RITA	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/556,246

Applicant(s)

JAY, GREGORY D.

Examiner

Rita Mitra

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,10-13,16,17,40,55,56,58 and 59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,10,13,16,17,40 and 55 is/are allowed.
- 6) ☒ Claim(s) 56,58 and 59 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Status of the Claims***

Applicants' amendment and response to office action dated February 17, 2004, filed on August 17, 2004 is acknowledged. Claims 3-9, 14-15, 18-39, 41-54 and 57 have been cancelled. Claims 1, 11 and 12 have been amended. Upon further review, claims 56, 58 and 59 found not allowable. Therefore, claims 1, 2, 10-13, 16, 17, 40, 55, 56, 58 and 59 are currently pending and are under examination.

### ***Response to Amendments and Remarks***

The objection to specification is withdrawn in view of amendment to the specification.

The previous rejection of claims 1, 2, 10-13, 16, 17 and 55 under **35 U.S.C. § 101, non-statutory** is withdrawn in view of Applicants' amendments to the claims.

The previous rejection of claim 18 under **35 U.S.C. § 112, first paragraph** is moot in view of the cancellation of the claim.

The previous rejection of claims 11 and 12 under **35 U.S.C. § 112, second paragraph** is withdrawn in view of the amendment to the claims.

The previous rejection of claims 1, 10, 40 under **35 U.S.C. § 103** as being unpatentable over Flannery, taken with Turner is withdrawn in view of amendment to claim 1.

The previous rejection of claims 41 and 57 under **35 U.S.C. § 103** as being unpatentable over Flannery, taken with Turner is moot in view of cancellation of the claims.

### ***Objection to Claims***

Claims 11 and 12 are objected to because words 'in vitro' and 'in vivo' are not italicized. An appropriate correction is requested.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (US 6433142, prior filing date August 8, 1989, issued August 13, 2002). Turner et al. teach human megakaryocyte stimulating factors (MSFS) capable of stimulating the growth and development of colonies of megakaryocytes. The reference teaches MSFs that include active fragments and alternatively spliced sequences derived from the cDNA sequence of the precursor protein encoding urinary meg-CSF (see Fig 1 and col 4, lines 59-67).

Turner et al. teach an MSF which contains all twelve exons (see col 10, lines 64-65). Turner's MSF is considered for the entire sequence of boundary lubricating polypeptide in the composition of claims 56, 57 and 58 because the claim requires amino acid sequence encoded by nucleic acid sequence comprising exon 1-12 of human megakaryocyte stimulating factor gene. It should be noted that claims 56, 58 and 59 recite the phrase "consisting essentially of," which is interpreted as "comprising of," that indicates that the exons other than what is explicitly claimed are also hidden in the claims. Turner's MSF sequence has 100% sequence identity to SEQ ID NO: 1 (see sequence alignment result 1, September 29, 1996, Database: genbank.seq, Accession NO: U70136). This addresses entire sequence of a boundary-lubricating polypeptide encoded by nucleic acids comprising all 12 exons of a human megakaryocyte stimulating factor gene of claims 56, 58 and 59.

Turner et al. also teach a purification and biochemical characterization of human megakaryocyte stimulating factor (MSF), see Example 1, col 26. The purified homogeneous protein obtained, having a specific activity ranging from about  $5 \times 10^7$  to  $2-5 \times 10^8$  dilution units per mg protein (see col 27). Therefore the protein is in a buffer or in water, thus addresses the composition of claims 56, 58 and 59 of the instant application.

Therefore, claims 56, 58 and 59 of the instant application are being anticipated by Turner et al.

***Conclusion***

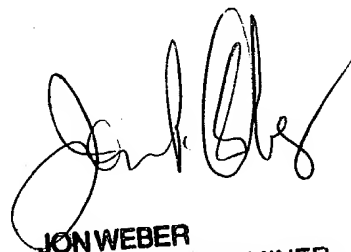
Claims 56, 58 and 59 are not allowable. Claims 11 and 12 are objected to. Claims 1, 2, 10, 13, 16, 17, 40 and 55 are allowable.

***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.



Rita Mitra, Ph.D.  
October 28, 2004



JON WEBER  
SUPERVISORY PATENT EXAMINER